510(k) Summary

Applicant:

Quidel Corporation
10165 McKellar Court
San Diego, California 92121
Telephone: 858-552-7910
Fax: 858-646-8045

Contact Information:

Ronald H. Lollar, Senior Director Clinical and Quality Affairs
1055 East State Street
Suite 100
Athens, Ohio 45701
740-589-3300 – Corporate number
740-589-3373 – Desk phone
740-593-8437 – Fax
lollar@dhiusa.com

Date of preparation of 510(k) summary:

December 20, 2011

Device Name:

Trade name – **Quidel Molecular Influenza A + B Assay**
Classification name – Respiratory viral panel multiplex nucleic acid assay
Product Code – OCC
Regulation – 21 CFR 866.3980

Legally marketed devices to which equivalence is claimed:

Gen-Probe Prodesse ProFlu+ (k092500)

The ProFlu™+ Assay is a multiplex Real-Time PCR (RT-PCR) *in vitro* diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to aid in the differential diagnosis of Influenza A, Influenza B and RSV viral infections in humans and is not intended to detect Influenza C.

Negative results do not preclude influenza or RSV virus infection and should not be used as the sole basis for treatment or other management

decisions. It is recommended that negative RSV results be confirmed by culture.

Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Intended Use:

The Quidel Molecular Influenza A+B assay is a multiplex Real Time RT-PCR assay for the in vitro qualitative detection and differentiation of influenza A and influenza B viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of influenza A and influenza B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay does not detect the presence of influenza C virus.

Negative results do not preclude Influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2010-2011 influenza season when influenza A/H3 and 2009 H1N1 influenza were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Device Description:

The Quidel Molecular Influenza A+B Assay detects viral nucleic acids that have been extracted from a patient sample using the NucliSENS® easyMAG® automated extraction platform. A multiplex real-time RT-PCR reaction is carried out under optimized conditions in a single tube generating amplicons for each of the target viruses present in the sample. This reaction is performed utilizing the Applied Biosystems® 7500 Fast Dx platform. Identification of influenza A occurs by the use of target specific primers and a fluorescent-labeled probe that hybridizes to a conserved influenza A sequence within the matrix protein gene. Identification of influenza B occurs by the use of target specific primers and fluorescent-labeled probes that will hybridize to a conserved influenza B sequence within the neuraminidase gene.

The following is a summary of the procedure:

1. **Sample Collection:** Obtain nasal swab and nasopharyngeal swab specimens using standard techniques from symptomatic patients. These specimens are transported, stored, and processed according to established laboratory procedures.

2. **Nucleic Acid Extraction:** Extract Nucleic Acids from the specimens with the NucliSENS easyMAG System following the manufacturer's instructions using the appropriate reagents. Use of other extraction systems with the Quidel Molecular Influenza A+B kit has not been validated. Validation of these systems is the responsibility of the end-user.
   Prior to the extraction procedure add 20 µL of the Process Control (PRC) to each 180 µL aliquot of specimen. The PRC serves to monitor inhibitors in the extracted specimen, assures that adequate amplification has taken place and that nucleic acid extraction was sufficient.

3. **Rehydration of Master Mix:** Rehydrate the lyophilized Master Mix using 135µL of Rehydration Solution. The Master Mix contains oligonucleotide primers, fluorophore and quencher-labeled probes targeting highly conserved regions of the influenza A and influenza B viruses as well as the process control sequence. The primers are complementary to highly specific and conserved regions in the genome of these viruses. The probes are dual labeled with a reporter dye attached to the 5-end and a quencher attached to the 3'-end. The rehydrated Master Mix is sufficient for eight reactions.

4. **Nucleic Acid Amplification and Detection:** Add 15 µL of the rehydrated Master Mix to each reaction plate well. 5µL of extracted nucleic acids (specimen with PRC) is then added to the plate well. Then place the plate into the ABI 7500 FastDx.

   Once the plate is added to the instrument, the assay protocol is initiated. This protocol initiates reverse transcription of the RNA targets generating

complementary DNA, and the subsequent amplification of the target amplicons occur. The Quidel Molecular Influenza A+B assay is based on TaqMan® chemistry, and uses an enzyme with reverse transcriptase, DNA polymerase, and 5'-3' exonuclease activities. During DNA amplification, this enzyme cleaves the probe bound to the complementary DNA sequence, separating the quencher dye from the reporter dye. This step generates an increase in fluorescent signal upon excitation by a light source of the appropriate wavelength. With each cycle, additional dye molecules are separated from their quenchers resulting in additional signal. If sufficient fluorescence is achieved by 35 cycles during the data collection stage of amplification, the sample is reported as positive for the detected nucleic acid.

Device Comparison

The Quidel Molecular Influenza A+B assay was compared to Prodesse ProFlu+ ("Comparator Device"). The characteristics of Quidel Molecular Influenza A+B assay ("Subject Device") and Prodesse ProFlu+ ("Predicate Device") are described in the table below:

Device Comparison		
Item	**Subject Device** Quidel Molecular Influenza A+B Assay	**Comparator Device** Prodesse ProFlu+
Intended Use	The Quidel Molecular Influenza A+B assay is a multiplex Real Time RT-PCR assay for the in vitro qualitative detection and differentiation of influenza A and influenza B viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of influenza A and influenza B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay does not detect the presence of influenza C virus.	The ProFlu™+ Assay is a multiplex Real-Time PCR (RT-PCR) *in vitro* diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to aid in the differential diagnosis of Influenza A, Influenza B and RSV viral infections in humans and is not intended to detect Influenza C.

Device Comparison		
Item	**Subject Device** Quidel Molecular Influenza A+B Assay	**Comparator Device** Prodesse ProFlu+
	Negative results do not preclude Influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2010-2011 influenza season when influenza A/H3 and 2009 H1N1 influenza were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	Negative results do not preclude influenza or RSV virus infection and should not be used as the sole basis for treatment or other management decisions. It is recommended that negative RSV results be confirmed by culture. Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Device Comparison		
Item	**Subject Device** Quidel Molecular Influenza A+B Assay	**Comparator Device** Prodesse ProFlu+
Assay Target	Influenza A virus, influenza B virus	Influenza A virus, influenza B virus, respiratory syncytial virus
Sample Types	nasal swab and nasopharyngeal swab	nasopharyngeal swab
Extraction Methods	bioMérieux easyMAG Automated Magnetic Extraction Reagents	Roche MagNA Pure LC Total Nucleic Acid Isolation Kit or the bioMérieux easyMAG Automated Magnetic Extraction Reagents
Assay Methodology	PCR-based system for detecting the presence or absence of viral RNA in clinical specimens	PCR-based system for detecting the presence or absence of viral RNA in clinical specimens
Detection Techniques	Multiplex assay using different reporter dyes for each target	Multiplex assay using different reporter dyes for each target
Viral Targets	Influenza A: Matrix Gene; Influenza B: conserved influenza B sequence within the neuraminidase gene	Influenza A: Matrix Gene; Influenza B: Non-structural NS1 and NS2
LoD	The analytical sensitivity (limit of detection or LoD) of the Quidel Molecular Influenza A+B assay was determined using quantified ($TCID_{50}$/mL) cultures of 3 influenza A strains (1 H1N1, 1 2009H1N1 and 1 H3N2), 3 influenza B strains, serially diluted in negative nasopharyngeal matrix. Each dilution was extracted using the NucliSENS easyMAG System and tested in replicates of 20 per	The analytical sensitivity (limit of detection or LoD) of the ProFlu+ Assay was determined using quantified ($TCID_{50}$/mL) cultures of 4 Influenza A (2 H1N1 and 2 H3N2), 2 Influenza B, 2 Respiratory Syncytial Virus Type A, and 2 Respiratory Syncytial Virus Type B strains serially diluted in nasopharyngeal clinical matrix. Each viral strain was extracted using the Roche

Device Comparison		
Item	**Subject Device** Quidel Molecular Influenza A+B Assay	**Comparator Device** Prodesse ProFlu+
	concentration of virus on the Applied Biosystems® 7500 Fast Dx platform. Analytical sensitivity (LoD), as defined as the lowest concentration at which 95% of all replicates tested positive, ranged from 10^1 to 10^0 $TCID_{50}$/mL.	MagNA Pure LC instrument and tested in replicates of 20 per concentration of virus. Analytical sensitivity (LoD), as defined as the lowest concentration at which 95% of all replicates tested positive, ranged from 10^2 to 10^{-1} $TCID_{50}$/mL.

Analytical Performance:

Precision/Reproducibility:

The reproducibility of the Quidel Molecular Influenza A and B assay was evaluated at 3 laboratory sites. Reproducibility was assessed using a panel of 4 simulated samples that included medium (5x LoD), low (2x LoD), high negative (.3x LoD) levels of influenza A virus, influenza B virus, and negative samples. Panels and controls were tested at each site by 2 operators for 5 days (triplicate testing x 2 operators x 5 days x 3 sites = 90 results per level for each virus). The panels and controls were extracted using the bioMérieux easyMAG system and tested on the ABI 7500Fast Dx.

Reproducibility Results										
Panel Member ID ($TCID_{50}$/mL)	Site 1			Site 2			Site 3			Total Results
	Results	AVE Ct	%CV	Results	AVE Ct	%CV	Results	AVE Ct	%CV	
Influenza A High Negative (1.44E+01)	4/30	34.03* (4 positive results)	2.0	8/30 (8 positive results)	34.07	1.9	0/30	N/A	N/A	12/90
Influenza A Low Positive (9.6E+01)	30/30	27.3	3.5	30/30	27.3	6.3	30/30	29.2	7.0	90/90
Influenza A Med Positive (2.4E+02)	30/30	25.3	2.9	30/30	25.2	5.1	30/30	26.8	5.5	90/90
Influenza A Negative	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90

Reproducibility Results										
Panel Member ID ($TCID_{50}$/mL)	Site 1			Site 2			Site 3			Total Results
	Results	AVE Ct	%CV	Results	AVE Ct	%CV	Results	AVE Ct	%CV	
Influenza B High Negative (1.3E+01)	0/30	N/A	N/A	3/30 (3 positive results)	34.2	1.2	0/30	N/A	N/A	3/90
Influenza B Low Positive (8.6E+01)	30/30	24.7	2.6	30/30	24.6	4.8	30/30	25.7	5.1	90/90
Influenza B Med Positive (2.2E+02)	30/30	22.9	2.0	30/30	22.7	2.6	30/30	23.5	2.9	90/90
Influenza B Negative	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
Influenza A Positive Control	30/30	12.4	1.6	30/30	11.8	2.2	30/30	12.1	1.1	90/90
Influenza B Positive Control	30/30	15.2	2.6	30/30	14.9	3.1	30/30	15.1	1.4	90/90
Negative Control	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90

* Ct values for positive tests

The data from the combined sites indicates that the Quidel Molecular assay generates reproducible results for both influenza A and influenza B viruses when tested with the ABI 7500 Fast Dx.

Limit of Detection

The analytical sensitivity (limit of detection or LoD) of the Quidel Molecular Influenza A+B assay was determined using quantified ($TCID_{50}$/mL) cultures of 3 influenza A strains (1 H1N1, 1 2009H1N1 and 1 H3N2), and 3 influenza B strains, serially diluted in negative nasopharyngeal matrix. Each dilution was extracted in replicates of 20 per concentration of virus using the NucliSENS easyMAG System and tested on the Applied Biosystems® 7500 Fast Dx platform. Analytical sensitivity (LoD) is defined as the lowest concentration at which 95% of all replicates tested positive.

Final $TCID_{50}$/mL LoD	
Strain	**7500 Dx**
A1/Mal/302/54	1.60E+01
A/Mexico/4108/2009	4.80E+01
A/Victoria/3/75	9.20E+01
B/Florida/04/2006	4.30E+01
B/RCHIN 8/05	1.20E+01
B/Malaysia/25/06/04	5.70E+00

Analytical reactivity (inclusivity)

The reactivity of the Quidel Molecular Influenza A+B assay was evaluated against multiple strains of influenza A and influenza B viruses. The clinical panel consisted of 10 Influenza A subtype H1N1, 2 Influenza A subtype 2009H1N1, 8 Influenza A subtype H3N2, 2 Influenza A subtype H5N1, 13 Influenza B, strains. An additional panel of non-clinical restricted isolates was also tested. Each panel member was extracted using the NucliSens easyMAG instrument and tested in triplicate.

The Quidel Molecular Influenza A+B assay detected 100% of the influenza A (38/38) and influenza B strains (15/15) at 10^2 to 10^3 $TCID_{50}$ levels including novel, pandemic and avian influenza A strains and recent circulating influenza B strains.

Clinical Panel Influenza A viruses				
Subtype	**Strain**	**$TCID_{50}$/mL**	(7500 Dx)	
			A	**B**
H1N1	H1N1 A/California/07/2009	1.45E+02	Positive	Negative
H1N1	A/New Caledonia/20/1999	1.12E+02	Positive	Negative
H1N1	A/New Jersey/8/76	3.80E+02	Positive	Negative
H1N1	A/PR/8/34	5.89E+02	Positive	Negative
H1N1	A/NWS/33	NA	Positive	Negative
H1N1	A/Denver/1/57	1.26E+02	Positive	Negative
H1N1	A/FM/1/47	3.80E+02	Positive	Negative
H1N1	A/Mexico/4108/2009	1.40E+02	Positive	Negative
H1N1	A1/Mal/302/54	4.19E+02	Positive	Negative
H1N1	A/Taiwan/42/06	3.39E+02	Positive	Negative
H1N1	A/Brisbane/59/07	7.24E+01	Positive	Negative
H1N1	A/Solomon Islands/3/06	1.41E+01	Positive	Negative
H3N2	A/Hong Kong/8/68	1.15E+02	Positive	Negative
H3N2	A/Wisconsin/67/2005	7.24E+02	Positive	Negative
H3N2	A/Aichi/2/68	4.17E+02	Positive	Negative

Clinical Panel Influenza A viruses				
Subtype	**Strain**	**$TCID_{50}$/mL**	(7500 Dx)	
			A	**B**
H3N2	A/Port Chalmers/1/73	4.57E+02	Positive	Negative
H3N2	A/Perth/16/2009	9.83E+02	Positive	Negative
H3N2	A/Uruguay/7/16/2007	1.03E+02	Positive	Negative
H3N2	A/Victoria/3/75	2.19E+02	Positive	Negative
H3N2	A/Brisbane/10/07	4.17E+02	Positive	Negative

Clinical Panel Influenza B viruses			
Strain	**$TCID_{50}$/mL**	(7500 Dx)	
		A	**B**
B/HongKong/5/72	6.67E+02	Negative	Positive
B/Panama/45/90	1.02E+02	Negative	Positive
B/Florida/02/2006	3.16E+02	Negative	Positive
B/Florida/04/2006	3.80E+02	Negative	Positive
B/Florida/07/2004	1.26E+02	Negative	Positive
B/Malaysia/25/06/04	3.41E+02	Negative	Positive
B/Maryland/1/59	1.15E+02	Negative	Positive
B/Allen/45	4.17E+02	Negative	Positive
B/Taiwan/2/62	1.51E+02	Negative	Positive
B/Russia/69	2.19E+02	Negative	Positive
B/Mass/3/66	1.38E+02	Negative	Positive
B/Lee/40	1.95E+02	Negative	Positive
B/GL/1739/54	6.30E+02	Negative	Positive

Non-clinical Restricted viruses				
Subtype	**Strain**	**$TCID_{50}$/mL**	(7500 Dx)	
			A	**B**

	A/WI/629-9/2008	2.00E+02	Positive	Negative
H3N2	A/WI/629-2/2008 (H3N2)	2.00E+02	Positive	Negative
H1N1	A/WI/629-S7(D02473)/2009 (H1N1pdm)	2.00E+02	Positive	Negative
H1N1	A/WI/629-S5 (D02312)/2009 (H1N1pdm)	2.00E+02	Positive	Negative
H2N2	A/Mallard/NY/6750/78 (H2N2)	2.00E+02	Positive	Negative
H7N3	A/Chicken/NJ/15086-3/94 (H7N3)	2.00E+02	Positive	Negative
H9N2	A/Chicken/NJ/12220/97 (H9N2)	2.00E+02	Positive	Negative
H4N8	A/Mallard/OH/338/86 (H4N8)	2.00E+02	Positive	Negative
H6N2	A/Chicken/CA/431/00 (H6N2)	2.00E+02	Positive	Negative
H8N4	A/Blue Winged Teal/LA/B174/86 (H8N4)	2.00E+02	Positive	Negative
H5N1	A/Anhui/01/2005(H5N1)-PR8-IBCDC-RG5	2.00E+02	Positive	Negative
H10N7	A/GWT/LA/169GW/88 (H10N7)	2.00E+02	Positive	Negative
H11N9	A/Chicken/NJ/15906-9/96 (H11N9)	2.00E+02	Positive	Negative
H12N5	A/Duck/LA/188D/87 (H12N5)	2.00E+02	Positive	Negative
H13N6	A/Gull/MD/704/77 (H13N6)	2.00E+02	Positive	Negative
H14N5	A/Mallard/GurjevRussia/262/82 (H14N5)	2.00E+02	Positive	Negative
H15N9	A/Shearwater/Australia/2576/79 (H15N9)	2.00E+02	Positive	Negative
H16N3	A/Shorebird/DE/172/2006(H16N3)	2.00E+02	Positive	Negative

Analytical specificity (cross-reactivity)

The analytical specificity of the Quidel Molecular Influenza A+B assay was evaluated by testing a panel consisting of 26 viral, 24 bacterial, and 1 yeast strain representing common respiratory pathogens or flora commonly present in nasopharynx. Bacteria and yeast were tested at concentrations of 10^5 to 10^{10} CFU/mL. Viruses were tested at concentrations of 10^3 to 10^6 $TCID_{50}$/mL. Samples were extracted using the NucliSens easyMAG instrument and tested in

triplicate. Analytical specificity of the Quidel Molecular influenza A+B assay was 100%.

Quidel Molecular influenza A+B assay Cross-reactivity Data			
Organism ID	**CFU/mL or $TCID_{50}$/mL**	Influenza A Result	Influenza B Result
hMPV A1	3.70E+04	Negative	Negative
hMPV B1	2.37E+04	Negative	Negative
RSV Long	4.40E+04	Negative	Negative
RSV Washington	1.75E+03	Negative	Negative
Adenovirus 1/Adenoid 71	5.67E+04	Negative	Negative
Coronavirus 229E	1.70E+06	Negative	Negative
Coronavirus OC43	1.67E+06	Negative	Negative
Coxsackievirus B4	2.43E+06	Negative	Negative
Coxsackievirus B5/10/2006	2.28E+06	Negative	Negative
Cytomegalovirus	8.76E+05	Negative	Negative
Echovirus 7	5.38E+08	Negative	Negative
Echovirus 9	1.50E+06	Negative	Negative
Echovirus 6	1.05E+08	Negative	Negative
Echovirus 11	1.50E+05	Negative	Negative
Enterovirus 71	2.68E+03	Negative	Negative
Enterovirus 70	1.66E+05	Negative	Negative
Epstein Barr Virus	5,000cp/mL	Negative	Negative
HSV Type 1 MacIntyre strain	1.95E+06	Negative	Negative
HSV Type 2 G strain	3.67E+06	Negative	Negative
Rubeola	3.78E+05	Negative	Negative
Mumps virus	8.43E+04	Negative	Negative
Parainfluenza Type 1	2.50E+05	Negative	Negative
Parainfluenza Type 2	2.20E+04	Negative	Negative
Parainfluenza Type 3	9.10E+05	Negative	Negative
Parainfluenza Type 4	9.57E+06	Negative	Negative
Varicella Zoster Virus	7.50E+02	Negative	Negative
Bordetella pertussis	1.04E+07	Negative	Negative
Bordetella bronchiseptica	2.55E+07	Negative	Negative
Chlamydia trachomatis	2.10E+05	Negative	Negative
Legionella pneumophila	2.05E+08	Negative	Negative
Mycobacterium intracellulare	6.90E+08	Negative	Negative
Mycobacterium tuberculosis	6.60E+07	Negative	Negative

Quidel Molecular influenza A+B assay Cross-reactivity Data			
Organism ID	**CFU/mL or $TCID_{50}$/mL**	Influenza A Result	Influenza B Result
Mycobacterium avium	1.36E+10	Negative	Negative
Haemophilus influenzae	5.90E+07	Negative	Negative
Pseudomonas aeruginosa	5.15E+07	Negative	Negative
Proteus vulgaris	2.65E+08	Negative	Negative
Proteus mirabilis	2.75E+07	Negative	Negative
Neisseria gonorrhoeae	2.15E+07	Negative	Negative
Neisseria meningitidis	1.85E+08	Negative	Negative
Neisseria mucosa	1.85E+08	Negative	Negative
Klebsiella pneumoniae	3.30E+07	Negative	Negative
Escherichia coli	6.80E+07	Negative	Negative
Moraxella catarrhalis	5.85E+07	Negative	Negative
Corynebacterium diphtheriae	6.0E+05	Negative	Negative
Lactobacillus plantarum	1.03E+08	Negative	Negative
Streptococcus pneumoniae	4.5E+07	Negative	Negative
Streptococcus pyogenes	2.05E+08	Negative	Negative
Streptococcus salivarius	2.50E+06	Negative	Negative
Staphylococcus epidermidis	2.6E+07	Negative	Negative
Staphylococcus aureus	5.15E+08	Negative	Negative
Candida albicans	1.07E+06	Negative	Negative

Clinical Performance:

A total of 1062 specimens were evaluated in this study (686-fresh, 376-frozen). Of the fresh specimens 373 specimens were nasal swabs, and 313 were nasopharyngeal swabs. The frozen specimens were comprised of 376 nasopharyngeal swabs.

Prospective Clinical Study

Six hundred and eighty six (686) fresh specimens (373 nasal swabs and 313 nasopharyngeal swabs) were tested by both the subject and comparator device for influenza A and influenza B virus viral RNA. Four of these specimens were invalid on initial testing with the subject device (0.6%). Re-testing of the specimens according to the Interpretation algorithm described above also yielded invalid results. Seventeen specimens were invalid on initial and repeat testing (as per the device's PI) on the comparator device (2.5%). Three specimens were invalid in both devices; therefore, a total 18 specimens were removed from additional analysis. The table below details the results for the remaining 668 specimens.

Influenza A			
Fresh nasal and nasopharyngeal swabs (N=668)	**Comparator: FDA Cleared RT-PCR device**		
Quidel Molecular	Positive	Negative	Total
Positive	139	8*	147
Negative	0	521	521
Total	139	529	668
			95% CI
Positive Percent Agreement	139/139	100%	97.4% to 100%
Negative Percent Agreement	521/529	98.5%	97.0% to 99.3%

*Seven specimens were negative by FDA Cleared RT-PCR device but positive for influenza A by sequence analysis. One specimen was negative by FDA Cleared RT-PCR device and negative for influenza A by sequence analysis.

Influenza B			
Fresh nasal and nasopharyngeal swabs (N=668)	**Comparator: FDA Cleared RT-PCR device**		
Quidel Molecular	Positive	Negative	Total
Positive	105	12*	117
Negative	5	546	551
Total	110	558	668
			95% CI
Positive Percent Agreement	105/110	95.5%	89.7% to 98.5%
Negative Percent Agreement	546/558	97.8%	96.3% to 98.9%

*Twelve specimens were negative by FDA Cleared RT-PCR device but positive for influenza B by sequence analysis.

The prospective clinical study had a dual infection rate for Influenza A and Influenza B of 1.8% (12/668) using the Quidel Molecular Influenza A + B Assay. Three of these dual infections were concordant with the FDA Cleared RT-PCR device comparator assay. Five of these dual infections were discordant with the Influenza A results from the FDA Cleared RT-PCR device comparator assay. Four of these dual infections were discordant with the Influenza B results from the FDA Cleared RT-PCR device comparator assay.

Retrospective Study

Three hundred and seventy six (376) frozen nasopharyngeal swabs were tested by both the subject and comparator devices for influenza A and influenza B virus viral RNA. Two of these specimens were invalid on initial testing with the subject device (0.5%). Re-testing of the specimens according to the Interpretation algorithm described above also yielded invalid results. Two specimens were invalid on initial and repeat testing (as per the device's PI) on the comparator device (0.5%). The invalid specimens were removed from performance analyses. The table below details the results for the remaining 372 specimens.

Influenza A			
Frozen nasopharyngeal swab (N=372)	**Comparator: FDA Cleared RT-PCR Device**		
Quidel Molecular	Positive	Negative	Total
Positive	37	0	37
Negative	0	335	335
Total	37	335	372
			95% CI
Positive Percent Agreement	37/37	100%	90.5% to 100%
Negative Percent Agreement	335/335	100%	98.9% to 100%

Influenza B			
Frozen nasopharyngeal swab (N=372)	**Comparator: FDA Cleared RT-PCR Device**		
Quidel Molecular	Positive	Negative	Total
Positive	37	2*	39
Negative	1	332	333
Total	38	334	372
			95% CI
Positive Percent Agreement	37/38	97.4%	86.2% to 99.9%
Negative Percent Agreement	332/334	99.4%	97.9% to 99.9%

*Two specimens were negative by FDA Cleared RT-PCR device but positive for influenza B by sequence analysis.

CONCLUSIONS

Quidel Molecular Influenza A + B Assay yielded good positive and negative percent agreement when compared to a 510(k) cleared molecular device.

Quidel Molecular Influenza A + B Assay yielded good positive and negative percent agreement for frozen nasopharyngeal swabs compared to a 510(k) cleared molecular device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Quidel Corporation
c/o Ronald H. Lollar
Senior Director Clinical and Quality Affairs
1055 East State Street, Suite 100
Athens, Ohio 45701

DEC 2 2 2011

Re: K112172
Trade/Device Name: Quidel Molecular Influenza A + B Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: Class II
Product Code: OCC, OOI
Dated: November 29, 2011
Received: November 30, 2011

Dear Mr. Lollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

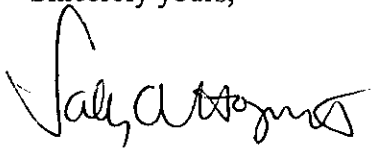
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): k112172

Device Name: Quidel Molecular Influenza A+B Assay

Indication for Use:

The Quidel Molecular Influenza A+B assay is a multiplex Real Time RT-PCR assay for the *in vitro* qualitative detection and differentiation of influenza A and influenza B viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of influenza A and influenza B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay does not detect the presence of influenza C virus.

Negative results do not preclude Influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2010-2011 influenza season when influenza A/H3 and 2009 H1N1 influenza were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Prescription Use		Over-The-Counter Use
X	AND/OR	
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K112172